EPA REGISTRATION FILE NUMBER 2724-372 Volume 2

NOTE TO FILES

January 16, 2018

The action assigned Decision number 499904 has not been closed due BPPD ongoing investigation into the regulatory process for reviewing/conducting risk assessment for pesticide intended for use in cattle feed.

Cheryl Greene

Greene, Cheryl

From:

Steve Spaulding <SSpaulding@central.com>

Sent:

Thursday, May 18, 2017 2:40 PM Nancy Huebl; Greene, Cheryl

To: Cc:

Hollis, Linda

Subject:

RE: Need Word formatted versions of the following documents.

Cheryl,

Nancy sent you over a week ago the following 4 outstanding labels reflecting all of the changes that you have requested for your final sign-off:

- 1. 2724-474- 0.4% S-Methoprene Premix
- 2. 2724-787 0.0025% S-Methoprene Block
- 3. 2724-372 0.02% S-Methoprene Granule
- 4. 2724-373 0.02% S-Methoprene Block

The changes to the labels are the same as you have approved on the other 3 labels; therefore, I would think it would be easy for you to expedite final approval. It is important to note that the original intention of the submissions were as formulation amendments to add an alternate source of MUP, so please do not forget to acknowledge approval of the CSF's that were submitted.

I have project meetings in Dallas again next week and I would like to remove this issue as a topic for discussion. Please help by wrapping this up once and for all.

Steven R. Spaulding
Senior Director of Regulatory Affairs
Central Garden & Pet
Wellmark International / Farnam Companies, Inc. / B2E Corp.
dba Central Life Sciences
(847) 330.5380 - office
(847) 544-6071 - cell
sspaulding@central.com

From: Nancy Huebl

Sent: Tuesday, May 09, 2017 8:48 AM

To: Greene, Cheryl < Greene. Cheryl@epa.gov>

Cc: Steve Spaulding <SSpaulding@central.com>; Bridget Maloney <bmaloney@central.com>

Subject: RE: Need Word formatted versions of the following documents.

Cheryl, per our phone call of this week, I am sending you the remainder of the labels revised in a similar fashion to the previously approved cattle labels that you've sent. I am including 2724-474 and 2724-787 in this email. I am attaching Word docs so if you have any comments, you can provide back to me. There is a hilited version and a clean version of each. I'll be sending the 2724-372 and 373 later this week.

Nancy

From: Greene, Cheryl [mailto:Greene.Cheryl@epa.gov]

Sent: Thursday, May 04, 2017 1:26 PM
To: Nancy Huebl NHuebl@central.com

Subject: RE: Need Word formatted versions of the following documents.

Importance: High

Hi Nancy:

Below is clarification on my earlier email. Your questions are in blue and my response is black font.

- Could you give me a date for the "label and CSF you submitted with your application". Nancy, the application was one of those submitted back in February 2015. The application is dated February 5, 2015. We received it on February 9. The application is for a CSF amendment to add 2724-840 as an alternate a.i. You actually did not submit a label amendment. However, as with the other applications submitted at that time, we need the label amended so that it is consistent with the other labels we've approved recently that carry the language about the users responsibility to adhere to FDA requirements. If it's any help, Kristin Hood actually signed the submission letter.
- The last EPA stamped approved label I have for 2724-474 is January 3, 2002. You are correct. The last
 amendment was approved in 2002 with two notification since then as you referenced. However, we do still
 need to review the label to get the new FDA language (see above) added.
- I have no March 3, 2005 last approved basic label. You are correct. What I read in our database as an amendment was actually a formulation amendment.

I hope this information helps. Please send me electronic copies of the CSF and the current label. Let me know if you have questions or need more 8information.

From: Greene, Cheryl [mailto:Greene.Cheryl@epa.gov]

Sent: Thursday, April 27, 2017 2:55 PM
To: Nancy Huebl NHuebl@central.com

Subject: RE: Need Word formatted versions of the following documents.

OPPS!! So sorry. I'm also working to get 2724-494 scanned and loaded into our database; I guess the numbers got jumbled in my brain. YES – I DO MEAN 2724-474!!!

From: Nancy Huebl [mailto:NHuebl@central.com]

Sent: Thursday, April 27, 2017 3:39 PM

To: Greene, Cheryl < Greene. Cheryl @epa.gov >

Cc: Steve Spaulding <SSpaulding@central.com>; Hollis, Linda <Hollis.Linda@epa.gov>; Bryceland, Andrew

<Bryceland.Andrew@epa.gov>; Burnett, Gina <Burnett.Gina@epa.gov>

Subject: RE: Need Word formatted versions of the following documents.

Cheryl, I assume you mean 2724-474 (not 494 which is already complete). Please confirm.

From: Greene, Cheryl [mailto:Greene.Cheryl@epa.gov]

Sent: Thursday, April 27, 2017 2:26 PM
To: Nancy Huebl NHuebl@central.com

Cc: Steve Spaulding <SSpaulding@central.com>; Hollis, Linda <Hollis.Linda@epa.gov>; Bryceland, Andrew

<<u>Bryceland.Andrew@epa.gov</u>>; Burnett, Gina <<u>Burnett.Gina@epa.gov</u>>

Subject: Need Word formatted versions of the following documents.

Importance: High

Hi Nancy:

I'm working on Wellmark's CSF and label amendment for 2724-494 (Altosid Cattle Concentrate). Please send me electronic copies of the label and CSF you submitted with your application. Please also send me an electronic copy of your last approved basic label (March 3, 2005).

NOTE: Please make sure that all of the documents are Word versions -not PDF. To save time I want to make comments directly on each of the documents. Let me know if you have questions or need more information.

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Greene, Cheryl

From:

Nancy Huebl < NHuebl@central.com>

Sent:

Monday, March 28, 2016 10:16 AM

To:

Hollis, Linda

Cc: Subject: Greene, Cheryl; Steve Spaulding; Casey White; Heather Friedli; Mark Taylor; Nate Brown 2724-372 ZOECON GRANULAR IGR CATTLE SUPPLEMENT LABEL AMENDMENT WITH

EPA COMMENTS (RESULT OF PENDING FORMULATION AMENDMENT)

Attachments:

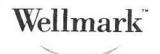
372 epa comments cover letter and 8570-1 316.pdf; epa amend w epa comments

316.doc; epa amend w epa comments clean 316.doc

Linda, per communication and phone conversations between Wellmark and EPA, attached are: a Word doc hilited to show requested changes, a clean Word doc for stamping, and a PDF of a cover letter and 8570-1 EPA form for the above cattle product. The revisions reflect EPA comments as a a result of pending formulation amendments for these products. We also look forward to receiving the approved formulation amendments. Thank you for your guidance on these actions.

Nancy Huebl Sr. Registration Specialist 847-330-5376

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Nancy Huebl

Senior Registration Specialist

Wellmark International

1501 E. Woodfield Rd Suite 200W Schaumburg IL 60173

847-330-5376 phone 847-330-5391 fax

mueblic central com

March 25, 2016

Document Processing Desk (NOTIF) Office of Pesticide Programs 7504P U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

ATTENTION: Linda Hollis/BPPD Branch Chief

SUBJECT:

LABEL AMENDMENT/EPA COMMENTS AS A

RESULT OF PENDING FORMULATION AMENDMENT

FOR ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT/EPA REG. NO. 2724-372

Dear Ms. Hollis:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted and a clean copy of labeling. This label amendment reflects EPA comments developed as a result of a pending formulation amendment. The main revisions are: update optional selenium statements to reflect maximum selenium content, add an ethoxyquin statement and to specify cattle use (versus generic animal).

If you have any questions, please, call me directly at 847/330-5376 or email me. Thank you for your assistance in this matter.

Yours sincerely.

WELLMARK INTERNATIONAL

Lancy Aluebl

Nancy Huebl

Sr. Registration Specialist

nhuebl@central.com

enclosure

Please read instructions on re	everse before comple form.		Forr proved, OMB No. 2	2070-0060. Approval expires 2-28-95
⊕ EPA	United States Environmental Protection Washington, DC 2046		X Registration Amendment Other	OPP Identifier Number
	Applica	tion for Pesticide - Section		
Company/Product Number		2. EPA Product Manager	**	3. Proposed Classification
Wellmark International/272	4-372	L. Hollis		o. i Topcacu Olasanicatori
Company/Product (Name) Wellmark International/Z	oecon Granular IGR Cattle Suppleme	PM # Biopesticides		X None Restricted
 Name and Address of Applic Wellmark International 1501 East Woodfield Road Schaumburg, Illinois 6017 		6. Expedited Review. (b)(i), my product is sim EPA Reg. No. Product Name	In accordance with FIFR iller or identical in compositi	on and labeling to:
Check if this is a	a new address			
		Section - II		
X Amendment - Explain belo	e to Agency letter dated	Agency I	nted labels in response to etter dated Application Explain below.	
redilication - Experi balo	•			
Label amendment to reflect	EPA comments as a result of a pending	formulation amendment Section - III		
		Section - III		
Material This Product Will Child-Resistant Packaging Yes X No	Unit Packaging X Yes No	Water Soluble Packagin Yes No	2. Type of Container Metal Plastic Glass	
* Certification must be submitted	If "Yes Unit No. per Packaging wgt. container 50 LB 1	If "Yes Unit No. pe Packaging wgt. contain	er X Paper	ecify)
3. Location of Net Contents Inf	formation 4. Size(s) Retail	Container	5. Location of Label Direction	15
	ontainer 50 lb		X On Label On Label Accomp	
6. Manner in Which Label is A	flixed to Product X Paper Slencil	glued	er Preprinted bag or sewn fe	
		Section - IV		
1. Contact Point (Complete	ttems directly below for identification of la	ndividual to be contacted, if neces	ssary, to process this applica	ation.)
Name		itle		none No. (Include Area Code)
Nancy Huebl	5	Sr. Registration Specialist	847-3	30-5376
	Certificat	ion		6. Date Application
I certify that the sta acknowledge that a under applicable to	atements I have made on this form and all att any knowingly false or misleading statements aw.	achments thereto are true, accurate my be punishable by fine or impriso	and complete. 1 nument or both	Received (Stamped)
2. Sanguey Janay		. Title Gr. Registration Specialist		
4. Typed Name	5	i. Date		
Nancy Huebl		25-Mar-16		

Label Review Sheet

FILENAME: Epa amend w epa comments 315

Supplement

COVERSHEET UPDATE:

March 2016

PRODUCT:

Zoecon Granular IGR Cattle EP

EPA REG. NO.:

2724-372

APPROVED

SUPERSEDES:

7-22-10

Page #	Description of Major Changes		
1	Feed Ingredients deleted "AAFCO approved" reference		
	Optional feed statement added for selenium (if required based on feed components		
	Added ethoxyguin statement		
2	Precautionary Statements Moved copper statement to Directions for Use, # and revised per EPA comments		
	Directions for Use: Added General Information to include ethoxyquin requirements		
	Feeding/Mgmt Instructions Updated per EPA comments for clarity and to specify cattle instead of animal		
3	Added information/phone number statement		
	Added registrant street address		

ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT

(Alternate Brand Name: ULTRALYX™ ULTRAMIN LOOSE MINERAL WITH ALTOSID® IGR)

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATED CATTLE

A [mineral] nutritional supplement containing S-methoprene* insect growth regulator for continuous feeding to cattle through the horn fly season

ACTIVE INGREDIENT:

S-Methoprene (CAS #65733-16-6)		0.02%
OTHER INGREDIENTS:		99.98%
	TOTAL	100.00%

GUARANTEED ANALYSIS

(WILL VARY DEPENDING ON GEOGRAPHIC AREA AND REGIONAL FEEDING

REQUIREMENT	
Calcium (CA), not less than	13.2%
Calcium (CA), not more than	
Phosphorus (P), not less than	7.0%
Salt (NaCl), not less than	25.0%
Salt (NaCl), not more than	30.0%
lodine (I), not less than	0.015%
Vitamin A, not less than	200,000
	USP units per pound

FEED INGREDIENTS

(AAFCO APPROVED FEED INGREDIENTS MAY VARY DEPENDING UPON NUTRITIONAL REQUIREMENTS IN DIFFERENT GEOGRAPHICAL REGIONS OF THE COUNTRY)

Vitamin A Acetate, D-Activated Animal Sterol (Source of Vitamin D₃-Stability Improved),
Dicalcium Phosphate, Defluorinated Phosphate, Calcium Carbonate, Low Fluorine Ground
Rock Phosphate, Soybean Meal, Salt, Iron Sulfate, Iron Oxide, Cobalt Carbonate, Silicon
Dioxide, Copper Carbonate, Petrolatum, Cane Molasses, Ethylene Diamine Dihydriodide,
Manganous Oxide, Zinc Oxide, Magnesium Oxide, Sodium Selenite

[This product contains supplemental selenium. Selenium can be fed at levels up to 120 ppm in a mixture for free-choice feeding at a rate not to exceed an intake of 3 mg per head per day. [[CFR Title 21 Sec 573 920 (c)(3)(ii)] This product contains ethoxyguin, a preservative

*As the Insect Growth Regulator ALTOSID®

KEEP OUT OF REACH OF CHILDREN CAUTION

Use this product only as specified on the back of the bag. See back panel for additional Precautionary Statements

EPA Reg. No. 2724-372

Lot Number: Net Weight: EPA Est. No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

This product contains high levels of copper. Consumption of this product by sheep or goats sould result in copper toxicity. (Optional text. If product contains over 10 ppm copper).

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

This product contains ethoxyquin, a preservative. The amount of ethoxyquin may vary according to the individual manufacturer's formulation and will not exceed the 150 ppm maximum limit established for ethoxyquin by FDA, per 21 CFR 573 380

FEEDING AND MANAGEMENT INSTRUCTIONS

Feed this product to cattle only. When used as directed Zoëcon® Granular IGR Cattle Supplement will provide sufficient S-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of horn fly season. Use the following management techniques to maintain continuous intake of Zoëcon Granular IGR Cattle Supplement at a level of ¹/₄ to ¹/₂ lb per 100 lb animal cattle body weight per month.

- Assure cattle are not starved for nutrients in Zoëcon Granular IGR Cattle Supplement by providing them prior to feeding Zoëcon Granular IGR Cattle Supplement.
- [This product contains added copper. Do not feed to cattle in close proximity to sheep or other species that have a low tolerance to supplemental copper.] (Statement required dependent on copper concentration.)
- 3. Offer cattle 50 lb of Zoëcon Granular IGR Cattle Supplement for every 15 head of cattle.
- Remove all other self-limiting nutritional supplements while the cattle are consuming this
 product.
- Locate Zoëcon Granular IGR Cattle Supplement where cattle congregate (watering, loafing, shade areas).
- 6. Replenish Zoëcon Granular IGR Cattle Supplement on a regular basis as needed.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>below</u> ¹/₄ lb per 100 lb <u>animal</u> <u>cattle</u> body weight per month increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>above</u> ¹/₂ lb per 100 lb <u>animal</u> <u>cattle</u> body weight reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.

Formatted: Font: Bold

 Introduction of this product after an adult horn fly infestation is established will require treatment of cattle with adulticides if immediate elimination of the adult fly population is desired.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store Zoëcon Granular IGR Cattle Supplement in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[For information, call 1-800-222-1222, 24 hours per day, 7 days per week.]

ALTOSID® Insect Growth Regulator and Zoëcon® are registered trademarks of Wellmark International.

Ultralyx™ is a trademark of Four Seasons Marketing, LLC

Wellmark International 1501 East Woodfield Road 200W

Schaumburg, Illinois 60173

Made in USA

Greene, Cheryl

From:

Greene, Cheryl

Sent:

Friday, March 24, 2017 7:33 PM

To:

'Steve Spaulding'; Hollis, Linda

Subject:

RE: S-Methoprene Feed-Thru Amendment Update

Hi Steve:

Hi Steve.

You should get 2724-494 Wednesday or Thursday. The others will follow. I will call you Monday to discuss.

From: Steve Spaulding [mailto:SSpaulding@central.com]

Sent: Thursday, March 23, 2017 5:17 PM

To: Hollis, Linda < Hollis.Linda@epa.gov>; Greene, Cheryl < Greene.Cheryl@epa.gov>

Subject: S-Methoprene Feed-Thru Amendment Update

Linda / Cheryl,

Here is where I think we stand on the S-Methoprene Cattle Feed-Thru Amendments in order of priority;

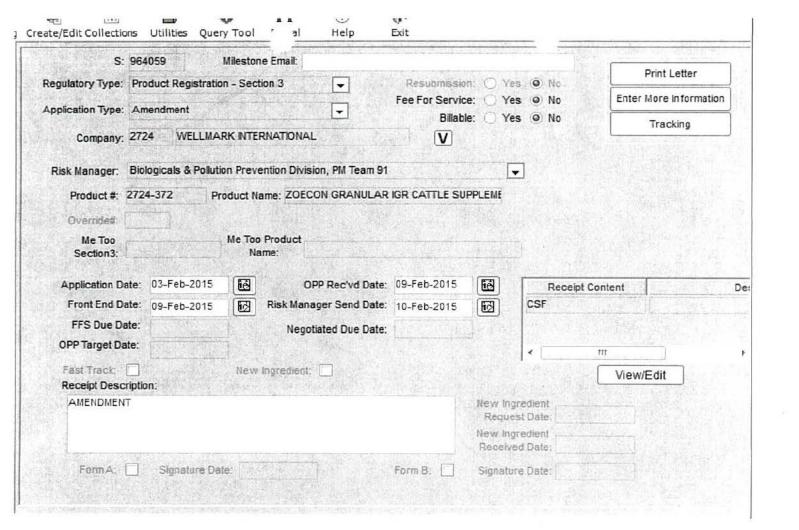
- 1. 2724-494 Approved initially April 15, 2016. Additional changes requested in November 2016 and Nancy provided revised label with changes on December 9, 2016. No feedback since then.
- 2724-495 Approved 2/6/17
- 3. 2724-492 Approved 2/27/17
- 2724-787 pending since February 2015
- 5. 2724-474 pending since February 2015
- 2724-372 pending since February 2015
- 7. 2724-373 pending since February 2015

I have a senior management meeting on April 6 and I am embarrassed and at a loss of how to explain why I cannot get these amendments approved, especially when most of the work has been done. Can you explain to me why these actions cannot be completed? It would really be nice not to discuss this again in the April 6 meeting. How do you justify this with your management?

Steven R. Spaulding
Senior Director of Regulatory Affairs
Central Garden & Pet
Wellmark International / Farnam Companies, Inc. / B2E Corp.
dba Central Life Sciences
(847) 330.5380 - office
(847) 544-6071 - cell
sspaulding@central.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

February 10, 2015

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

JAMES MCFADDEN, PH.D. WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173

PRODUCT NAME: ZOECON GRANULAR IGR CATTLE SUPPLEMENT

COMPANY NAME: WELLMARK INTERNATIONAL

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 2724-372 EPA RECEIPT DATE: 02/09/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division



Fee for Service

{964050u~

This package includes the following	for Division
New RegistrationMemore AmendmentStudies?□ Fee Waiver?	○ AD • BPPD ○ RD
□ volpay % Reduction:	Risk Mgr. 91
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	96405 9 Concerted by \$3 2724-372 2/9/2015
This item is NOT subject to	o FFS action.
Action Code: Requested: Granted: Amount Due: \$	Parent/Child Decisions:
Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer: /m/rw Byce/and Remarks:	Date: 2-/0-15

Inert ingredient information may be entitled to confidential treatment



Kristin Hood

Regulatory Affairs Specialist

Wellmark International

1501 E. Woodfield Rd Suite 200W

Schaumburg, IL 60173

847-330-5360 phone 847-330-5391 fax

khood@central.com

February 3, 2015

Andrew Bryceland

Biopesticides Division Document Processing Desk (AMEND) Office of Pesticide Programs (7511P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

Subject:

Formulation Amendment to Add Alternate Source of (S)-Methoprene MUP, RF2222 CCG (EPA Reg. No. 2724-840) to Zoecon Granular IGR Cattle Supplement (EPA

Reg. No. 2724-372)

(Contains Confidential Business Information)

Dear Mr. Bryceland:

This formulation amendment for the Wellmark product with EPA Reg. No. 2724-372 is submitted to add an alternate source of the (S)-Methoprene MUP (RF2222 CCG; EPA Reg. No. 2724-840) as a new Alternate (2) formula. RF2222 CCG was recently approved by the EPA on 11/24/2014, therefore Alternate Formulas need to be submitted for all end-use products that are formulated with this MUP. RF2222 CCG contains 2% (S)-Methoprene which is equivalent to the current source RF2038 Granule (EPA Reg. No. 2724-502) on the current alternate formula 1. RF2222 CCG (EPA Reg. No. 2724-840) contains

Two copies of the new Alternate (2) CSF are submitted, along with one copy of the existing basic formula and form 8570-1. The 8570-27 form is not required because Wellmark International is the registrant of (S)-Methoprene technical.

If you have any questions regarding this submission or need additional information, please contact me by phone or e-mail as noted above.

Regards,

Kristin Hood

Regulatory Affairs Specialist

KINTPHOS

encl.

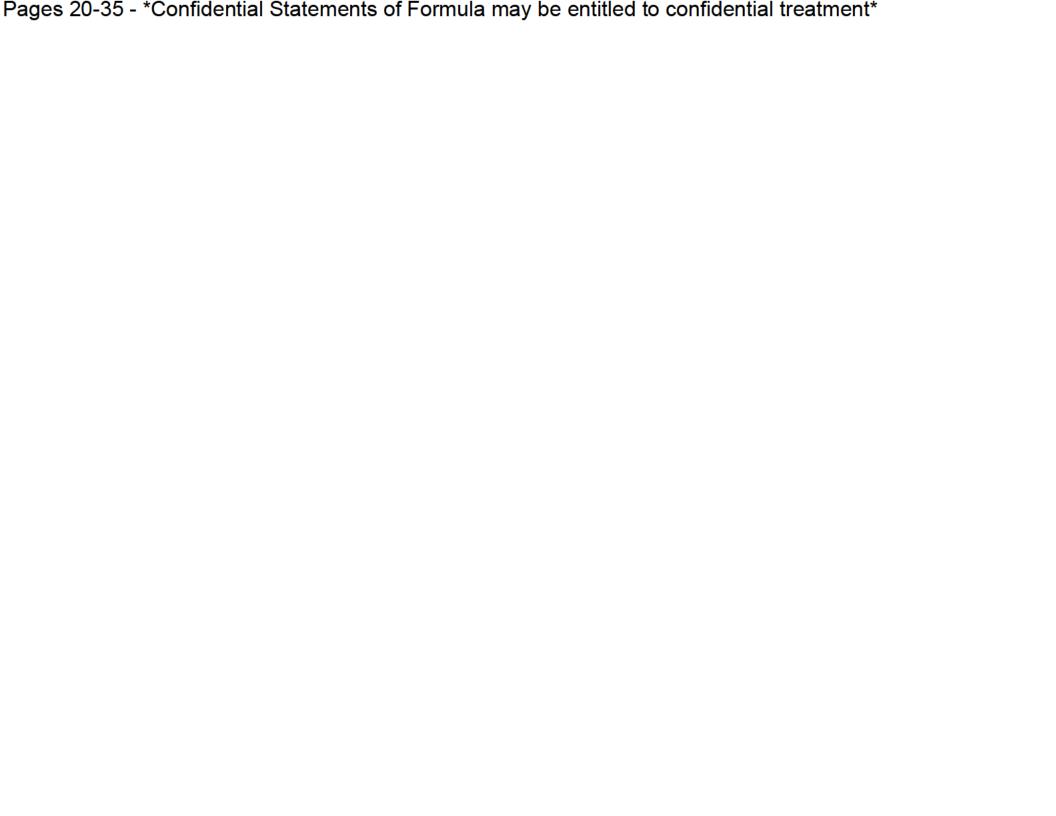
Inert ingredient information may be entitled to confidential treatment

Please read instructions on	reverse before completing i				Form /	Аррі .	OMB No. 20	70-0060. Approv	al expires 2-28-9
⊕ EPA		United States tal Protection A hington, DC 20460	gency		1	Regist Amend Other		OPPId	entifier Number
		Applicatio	n for Pesticide	- Secti	on I			· ·	
Company/Product Number Wellmark International			EPA Produc A. Brycelance	Constitution of the	r			3. Proposed Clas	sification
Company/Product (Name) Wellmark International/ Company to 100 Section 100 Sec			PM#					✓ None	Restricted
Zoecon Granular IGR Sup	iplement licant / Registrant (Include ZIF	Code)							
Wellmark International		Code	Classic Street					Section 3(C)(3 sometimes and labeling	
1501 East Woodfield R Schaumburg, IL 60173			■ EPA Reg. N Product Nar	V4					
Check if this is	a new address		il.						
			Section - II						
✓ Amendment - Explain be Resubmission in response	low. se to Agency letter dated			Agenc	orinled labe y letter dat oo" Applica		se to		
Notification - Explain belo	ow.			Other	- Explain b	elow			
Explanation: United	onal page(s) if necessary. (For		250				18 51-0		
RF2038 Granule has submitted that are formul		222 CCG was redule. For questions	s, please contact	y the E Kristin I	PA on 11 Hood, Tel	/24/2014, : 847-330	therefore -5360; E-N	alternate formu Mail: khood@ce	las need to be intral.com
CATALOG CATALO	22 2 8 - 7207		Section - III						
1. Material This Product Wil	4 65-50-65 N 20			were					
Child-Resistant Packaging	Unit Packaging	VV	ater Soluble Packa	jing	1 3	2. Type of (Container		
Yes	Yes		Yes			F / 1	Metal		
✓ No	✓ No		No Plastic Glass						
* Certification must be submitted	If "Yes Unit Packaging wgt.	11000000	No. per If *Yes Unit No. per			aper Other (Specif	у)		
3. Location of Net Contents In	formation 4	. Size(s) Retail Conta	ainer		5, Locati	on of Label	Directions		
✓ Label C	ontainer 5	0 lb			[<	On Label	Accompany	ing Product	
6. Manner in Which Label is A	ffixed to Product	✓ Lithograph Paper glued Stenciled		— Oil	her		_		-
			Section - IV						
1. Contact Point (Complete	items directly below for ide	ntification of individ	ual to be contacted	l, if neces	sary, to p	rocess this	application	.)	
Name Kristin Hood		Title Regula	atory Affairs Sp	ecialist			Telephone (847) 33	No. (Include Area 80-5360	Code)
	stements I have made on this is any knowingly false or misleadw.							6. Date Applicat Received (Star	nped)
2. Signature	110	3. Title							
4. Typed Name	Ook		atory Affairs Sp	ecialist					
Kristin Hood		5. Date	b-2015						

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow - Applicant copy



Print Form





Environmental Protection Agency

Office of Pesticide Programs (7505C) Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor

90
tributor product labels
stributor Product Name geland Early Season 6 Breeder Mineral w/Altosid
1

1080 County Road F West Shoreview, MN 55126-2910

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice. Signature and Title of Distributor Manager, Regulatory Affairs Registrant l egree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this

Notice.

Hulbl

Print Form

United States



Environmental Protection Agency

Office of Pesticide Programs (7505C) Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

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This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product 2724-372	Distributor Company Number 1990		
Note: Do not subm	it distributor product labels		
Name of Registered Product (basic product name accepted by EPA) Zoecon Granular IGR Cattle Supplement	Distributor Product Name Rangeland Year Round 8 Breeder Complete Mineral w/Altosid		
Name and Address of Distributor (Type: include 7IP code)			

Land O'Lakes Purina Feed LLC 1080 County Road F West Shoreview, MN 55126-2910

Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- 5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
- All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice. Signature and Title of Distributor Manager, Regulatory Affairs

Registrant

agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

egistration Specialist

United States



EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

Environmental Protection Agency

Office of Pesticide Programs (7505C) Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number				
2724-372					
Note: Do not subm	it distributor product labels				
Name of Registered Product (basic product name accepted by EPA)	Distributor Product Name				
Zoecon Granular IGR Cattle Supplement Rangeland Year Round 8 Breeder Mineral Altosid					
Name and Address of Distributor (Type; include ZIP code)					
Land O'Lakes Purina Feed LLC 1080 County Road F West					
Shoreview, MN 55126-2910					
Read All Conditions	Before Signing				
 the registered basic product. The labeling for the distributor product must bear the specific claims may be deleted if by doing so, no othe The product must remain in the manufacturer's unbroined. The label must bear the EPA registration number of the company number. Distributor product labels must bear the name and addron", "distributed by"; or "sold by" to show that All conditions of the basic registration apply equally to 	ckaged by the same person who manufactures and packages same claims as the basic product, provided, however, that or changes to the label are necessary. It is basic product, followed by a hyphen and the distributor's dress of the distributor qualified by such terms as "packed"				
Distrit	butor				
We intend to market our product under the Distributor Product Name sp	ecified above, subject to the conditions specified on this Notice.				
Signature and Title of Distributor	Date				
Manager, Regulatory Affairs	6/2/13				
Regis	strant				
I agree that the distributor named above may distribute and sell the Dist Notice.	tributor Product specified above, subject to the concitions specified on this				
Signature and Title of Registrant Lenior Registration	Specialiso June 34, 2010				
FPA Form 8570-5 (Rev. 8-94). Previous editions are obsolete	White - EPA				

MATERIAL TO BE ADDED TO JACKET

REG #: 2724-372

Description: Notification - Accepted

if a	oplicable, check all that are attached:	
	new stamped accepted label	Se
	new CSF	Send to
	notification	50 0
	other:	SC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the <u>CSF folder</u> (if returning jacket) or covered with a <u>red CBI sheet</u> (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer:	Colin Walsh	Date: _7/	/22/2010
Phone:	(703) 308-0298	Division:	BPPD

WWIROM WALL PROTECTION

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 22, 2010

Laura Doolin Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173

RE: I

Product Name: Zoecon Granular IGR Cattle Supplement

EPA Reg. No: 2724-372

Application for Label Notification dated July 7, 2010 to add "mineral" as

optional text to a label claim.

Dear Ms. Doolin:

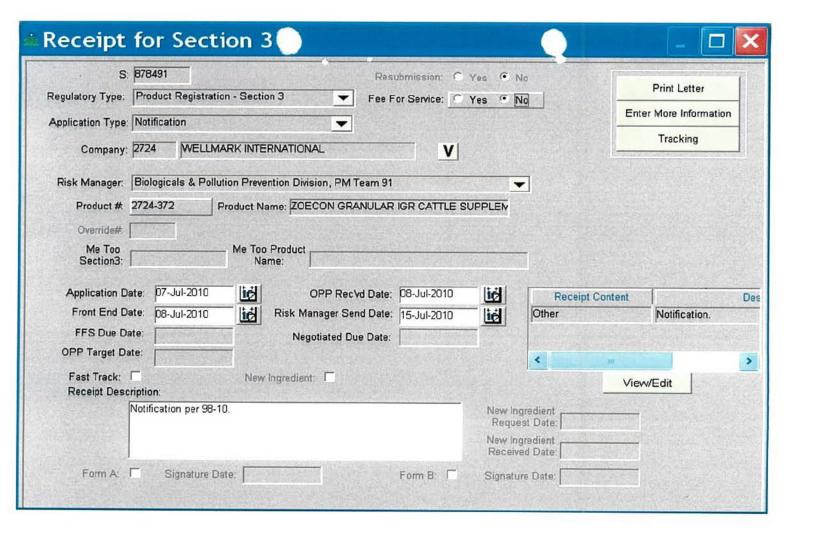
The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PR Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)



Recol ACB 19/16/10

ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT

(Alternate Brand Name: ULTRALYX™ ULTRAMIN LOOSE MINERAL WITH ALTOSID® IGR)

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATED CATTLE

A [mineral] nutritional supplement containing S-methoprene* insect growth regulator for continuous feeding to cattle through the horn fly season

ACTIVE INGREDIENT:

S-Methoprene (CAS #65733-16-6)		0.02%
OTHER INGREDIENTS:		
THE PROPERTY OF THE PARTY OF THE PROPERTY OF T	TOTAL	100.00%

GUARANTEED ANALYSIS

(WILL VARY DEPENDING ON GEOGRAPHIC AREA AND REGIONAL FEEDING REQUIREMENTS)

i i i i i i i i i i i i i i i i i i i	
Calcium (CA), not less than	
Calcium (CA), not more than	
Phosphorus (P), not less than	7.0%
Salt (NaCl), not less than	25.0%
Salt (NaCl), not more than	
lodine (I), not less than	0.015%
Vitamin A, not less than	200,000 =
	USP units per pound

FEED INGREDIENTS

(AAFCO APPROVED FEED INGREDIENTS MAY VARY DEPENDING UPON NUTRITIONAL REQUIREMENTS IN DIFFERENT GEOGRAPHICAL REGIONS OF THE COUNTRY)

Vitamin A Acetate, D-Activated Animal Sterol (Source of Vitamin D₃-Stability Improved),

Dicalcium Phosphate, Defluorinated Phosphate, Calcium Carbonate, Low Fluorine Ground Rock Phosphate, Soybean Meal, Salt, Iron Sulfate, Iron Oxide, Cobalt Carbonate, Silicon Dioxide, Copper Carbonate, Petrolatum, Cane Molasses, Ethylene Diamine Dihydriodide, Manganous Oxide, Zinc Oxide, Magnesium Oxide, Sodium Selenite

KEEP OUT OF REACH OF CHILDREN CAUTION

Use this product only as specified on the back of the bag. See back panel for additional Precautionary Statements

EPA Reg. No. 2724-372

Lot Number: Net Weight: **Notification Accepted**

EPA Est. No.

Date: JU

JUL 2 2 2010

Reviewer: C. Walsh

^{*}As the Insect Growth Regulator ALTOSID®

Morting Account

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

This product contains high levels of copper. Consumption of this product by sheep or goats could result in copper toxicity. (Optional text - If product contains over 10 ppm copper).

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FEEDING AND MANAGEMENT INSTRUCTIONS

When used as directed Zoëcon® Granular IGR Cattle Supplement will provide sufficient S-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of horn fly season. Use the following management techniques to maintain continuous intake of Zoëcon Granular IGR Cattle Supplement at a level of ¹/₄ to ¹/₂ lb per 100 lb animal body weight per month.

- 1. Assure cattle are not starved for nutrients in Zoëcon Granular IGR Cattle Supplement by providing them prior to feeding Zoëcon Granular IGR Cattle Supplement.
- 2. Offer cattle 50 lb of Zoëcon Granular IGR Cattle Supplement for every 15 head of cattle.
- 3. Remove all other self-limiting nutritional supplements.
- 4. Locate Zoëcon Granular IGR Cattle Supplement where cattle congregate (watering, loafing, shade areas).
- 5. Replenish Zoëcon Granular IGR Cattle Supplement on a regular basis as needed.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>below</u> ¹/₄ lb per 100 lb animal body weight per month increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- 7. If intake of Zoëcon Granular IGR Cattle Supplement is <u>above</u> ¹/₂ lb per 100 lb animal body weight reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- 8. Introduction of this product after an adult horn fly infestation is established will require treatment of cattle with adulticides if immediate elimination of the adult fly population is desired.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store Zoëcon Granular IGR Cattle Supplement in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ALTOSID® Insect Growth Regulator and Zoëcon® are registered trademarks of Wellmark International.

Ultralyx™ is a trademark of Four Seasons Marketing, LLC

Wellmark International Schaumburg, Illinois 60173

Made in USA

91

Wellmark Inc. ational

1501 East Woodfield Road, Suite 230 West Schaumburg, Illinois 60173 847 330 5300 www.wellmarkinternational.com



July 7, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Linda Hollis/BPPD Branch Chief

SUBJECT: NOTIFICATION PER 98-10 Section II N/ZOËCON® GRANULAR IGR CATTLE

SUPPLEMENT/EPA REG. NO. 2724-372

Dear Ms. Hollis:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted labeling to serve as notification per 98-10. The added text represents optional text added to a marketing claim (for subregistrant), no other changes were made to the label. This action is not a PRIA action and does not require any fee.

If you have any questions, please, call me directly at 847/330-5384 or email me. Thank you for your assistance in this matter.

Yours sincerely, WELLMARK INTERNATIONAL

Zaura Doolin

Laura Doolin Regulatory Intern Idoolin@central.com

enclosure

Please read instructions on re	everse before completin	g íc		Form	Apr. '. OMB No.	2070-0060. Approval expires 2-28-95			
⇔ EPA		United States ental Protection A ashington, DC 20460		X	Registration Amendment	OPP Identifier Number			
		Application	on for Pesticide	- Section I					
1. Company/Product Number			2. EPA Product			3. Proposed Classification			
Wellmark International/2724-372			Linda Hollis						
Company/Product (Name) Wellmark International/Zoecon Granular IGR Cattle Supplement			PM#91 Biopesticides	PM # 9 \ Restricted					
5. Name and Address of Appli	cant / Registrant (Include	ZIP Code)	6. Expedited	Review. In a	ccordance with FIFE	RA Section 3(C)(3)			
Wellmark International			(b)(i), my pro	duct is similar o	r identical in compos	sition and labeling to:			
1501 East Woodfield Ro	ad, Suite 200W		AVAINAMENT TO AN			3			
Schaumburg, Illinois 60	173		EPA Reg. N	0					
			Product Nan	ne					
Check if this is a	a new address			11000-6					
			Section - II						
			COCCON II	75					
Amendment - Explain belo				Agency letter da "Me Too" Applic	MOI	ification Accepted			
X Notification - Explain below	w.			Other - Explain below. Date: JUL 2 2 2010					
	nal page(s) if necessary.					ewer: C. Walch			
This notification is consist labeling or the confidential statement to EPA. I furthe in violation of FIFRA and I	I statement of formula r understand that if thi	of this product. I un s notification is not	derstand that it is a consistent with the	violation of 18 terms of PR Not	J.S.C. Sec. 1001 to ice 98-10 and 40 CF	s have been made to the willfully make any false FR 152.46, this product may be			
			Section - III						
1. Material This Product Will	be Packaged In:								
Child-Resistant Packaging	Unit Packaging		Water Soluble Packaç	ging	2. Type of Container				
Yes	X Yes		Yes X No		X Metal Plastic				
\ No		WAR WAR IN		40/2007	Glass				
* Certification must be submitted	If "Yes Unit Packaging wgt. 50 lbs		"Yes Unit ackaging wgt	No. per container	X Paper Other (Spe	ecify)			
3. Location of Net Contents Inf	ormation	4. Size(s) Retail Co	ntainer	5. Loca	ation of Label Directions	3			
X Label Co		1000	On Label On Label Accompa						
6. Manner in Which Label is Affixed to Product Lithogra Paper gl				Other	On Laber Accompa	anying Product			
		X Stenciled							
			Section - IV						
1. Contact Point (Complete	items directly below for	identification of indiv	ridual to be contacted	d, if necessary, to	process this applicati	ion.)			
Name		Title			Telepho	one No. (Include Area Code)			
Laura Doolin		Reg	julatory Intern		(847)-	330-5384			
leadify that the -t-	tomosto I have wede "	Certification				Date Application Received			
acknowledge that a	tements I have made on t my knowingly false or mis	leading statements my	be punishable by fine	or imprisonment or	plete. I both	(Stamped)			

3. Title

5. Date

06-Jul-10

Regulatory Intern

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

2. Signature Auron Duolin

4. Typed Name

Laura Doolin

White - EPA File Copy (original)

Please read instructions on rev	verse before completing t		Form App. 1. OMB N	10. 2070-0060. Approval expires 2-28-95
⇔ EPA	United States Environmental Protecti Washington, DC 20	tion Agency	Registration Amendment Other	OPP Identifier Number
	Appli	ication for Pesticide - Section	on I	
Company/Product Number Wellmark International/2724	4-372	EPA Product Manager Linda Hollis		3. Proposed Classification
Company/Product (Name) Wellmark International/Zo Supplement	oecon Granular IGR Cattle	PM# 9 \ Biopesticides		X None Restricted
5. Name and Address of Application Wellmark International 1501 East Woodfield Road Schaumburg, Illinois 6017	73	E CONTROL OF THE CONT	r. In accordance with FI imilar or identical in comp	position and labeling to:
		Section - II	144	· · · · · · · · · · · · · · · · · · ·
This notification is consisten labeling or the confidential s statement to EPA. I further u	to Agency letter dated	Agency "Me To Other - d section II.) and EPA regulations at 40 CFR 15. I understand that it is a violation of the consistent with the terms of	Rev 52.46, and no other chang n of 18 U.S.C. Sec. 1001 I PR Notice 98-10 and 40 I	viewer: C. Walsh. ges have been made to the
		Section - III		*
1. Material This Product Will be	e Packaged In:			
Child-Resistant Packaging Yes No	Unit Packaging X Yes No	Water Soluble Packaging Yes X	2. Type of Containe Metal Negation Glass	er
* Certification must be submitted	If "Yes Unit No. per Packaging wgt. No. per container 50 lbs	If "Yes Unit No. p Packaging wgt. conta	per X Paper	ipecify)
	tainer 50 lbs			ons npanying Product
Manner in Which Label is Affix	A CONTROL OF THE PROPERTY OF T		ner	
		Section - IV		
	ems directly below for identification of i			
Name Laura Doolin		Title Regulatory Intern		phone No. (Include Area Code) 2)-330-5384 cress
I certify that the staten acknowledge that any under applicable law.	Certifica ments I have made on this form and all at y knowingly false or misleading statements	ttachments thereto are true, accurate a	and complete. I nment or both	6. Date Application Received (Stamped)
2. Signature DU	olin	3. Title Regulatory Intern	c cc:	20 C C C
4. Typed Name Laura Doolin		5. Date 06-Jul-10	-	ecci.



c 7/22/2010 c

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 22, 2010

Laura Doolin Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, IL 60173

RE: Product Name: Zoecon Granular IGR Cattle Supplement

EPA Reg. No: 2724-372

Application for Label Notification dated July 7, 2010 to add "mineral" as

optional text to a label claim.

Dear Ms. Doolin:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PR Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT

(Alternate Brand Name: ULTRALYX™ ULTRAMIN LOOSE MINERAL WITH ALTOSID® IGR)

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATED CATTLE

A [mineral] nutritional supplement containing S-methoprene* insect growth regulator for continuous feeding to cattle through the horn fly season

ACTIVE INGREDIENT:

S-Methoprene (CAS #65733-16-6)	0.02%
OTHER INGREDIENTS:	99.98%
TOT	AL 100.00%

GUARANTEED ANALYSIS (WILL VARY DEPENDING ON GEOGRAPHIC AREA AND REGIONAL FEEDING REQUIREMENTS)

inegonite interview	
Calcium (CA), not less than	
Calcium (CA), not more than	
Phosphorus (P), not less than	7.0%
Salt (NaCl), not less than	25.0%
Salt (NaCl), not more than	30.0%
lodine (I), not less than	0.015%
Vitamin A, not less than	200,000
	USP units per pound

FEED INGREDIENTS

(AAFCO APPROVED FEED INGREDIENTS MAY VARY DEPENDING UPON NUTRITIONAL REQUIREMENTS IN DIFFERENT GEOGRAPHICAL REGIONS OF THE COUNTRY)

Vitamin A Acetate, D-Activated Animal Sterol (Source of Vitamin D₃-Stability Improved),

Dicalcium Phosphate, Defluorinated Phosphate, Calcium Carbonate, Low Fluorine Ground Rock Phosphate, Soybean Meal, Salt, Iron Sulfate, Iron Oxide, Cobalt Carbonate, Silicon Dioxide, Copper Carbonate, Petrolatum, Cane Molasses, Ethylene Diamine Dihydriodide, Manganous Oxide, Zinc Oxide, Magnesium Oxide, Sodium Selenite

KEEP OUT OF REACH OF CHILDREN CAUTION

Use this product only as specified on the back of the bag. See back panel for additional Precautionary Statements

EPA Reg. No. 2724-372

Lot Number: Net Weight: **Notification Accepted**

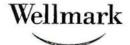
Date: JUL 2 2 2010

Reviewer: C. Walsk

^{*}As the Insect Growth Regulator ALTOSID®

Wellmark In ... ational

1501 East Woodfield Rood, Suite 200 West Schaumburg, Illinois 60173 847 330 5300 www.wellmarkinternational.com



2124/3/2

July 7, 2010

Document Processing Desk (NOTIF) Office of Pesticide Programs 7504P U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

ATTENTION: Linda Hollis/BPPD Branch Chief

SUBJECT:

PNOTIFICATION PER 98 10 Section II N/ZOECON® GRANULAR IGR CATTLE SUPPLEMENT/EPA/REGENO/2724-3724

Dear Ms. Hollis:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted labeling to serve as notification per 98-10. The added text represents optional text added to a marketing claim (for subregistrant), no other changes were made to the label. This action is not a PRIA action and does not require any fee.

If you have any questions, please, call me directly at 847/330-5384 or email me. Thank you for your assistance in this matter.

Yours sincerely, WELLMARK INTERNATIONAL

Laura Doulin

Laura Doolin Regulatory Intern Idoolin@central.com

enclosure



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

This product contains high levels of copper. Consumption of this product by sheep or goats could result in copper toxicity. (Optional text - If product contains over 10 ppm copper).

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FEEDING AND MANAGEMENT INSTRUCTIONS

When used as directed Zoëcon® Granular IGR Cattle Supplement will provide sufficient S-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of horn fly season. Use the following management techniques to maintain continuous intake of Zoëcon Granular IGR Cattle Supplement at a level of ¹/₄ to ¹/₂ lb per 100 lb animal body weight per month.

- Assure cattle are not starved for nutrients in Zoëcon Granular IGR Cattle Supplement by providing them prior to feeding Zoëcon Granular IGR Cattle Supplement.
- 2. Offer cattle 50 lb of Zoëcon Granular IGR Cattle Supplement for every 15 head of cattle.
- Remove all other self-limiting nutritional supplements.
- 4. Locate Zoëcon Granular IGR Cattle Supplement where cattle congregate (watering, loafing, shade areas).
- 5. Replenish Zoëcon Granular IGR Cattle Supplement on a regular basis as needed.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>below</u> ¹/₄ lb per 100 lb animal body weight per month increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>above</u> ¹/₂ lb per 100 lb animal body weight reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- 8. Introduction of this product after an adult horn fly infestation is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established will require ence treatment of cattle with adulticides if immediate elimination of the adult fly population is established.

....

.....



STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store Zoëcon Granular IGR Cattle Supplement in a cool place.

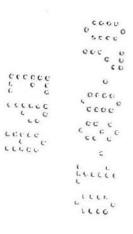
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ALTOSID® Insect Growth Regulator and Zoëcon® are registered trademarks of Wellmark International.

Ultralyx™ is a trademark of Four Seasons Marketing, LLC

Wellmark International Schaumburg, Illinois 60173

Made in USA



Label Review Sheet

FILENAME: Epa notif claim 710.doc COVERSHEET July 2010

UPDATE:

PRODUCT: Zoecon Granular IGR Cattle EPA REG. NO.: 2724-372

Supplement

APPROVED Notif Submitted 7/7/10 SUPERSEDES: 2/16/10

OVERVIEW: Adding optional text to a marketing claim for subregistrant

Page #	Description of Major Changes	
1	Adding [mineral] as optional text to a marketing claim	

Material to be added to an e-Jacket

	Reg. No 2 29-372						
1.	Placement within the e-Jacket:						
X	Default: chronological top						
♦	Other: (PDF page number, i.e., "before page 45")						
2.	Is this material:						
	Newly stamped accepted label						
	Notification - acceptable						
	♦ New CSF						
	♦ Other:						
mater	Attach this notice on top of the material. It must oped all together, NOT STAPLED. Then give the rial with this coversheet to staff in the Information ces Center (Room S-4900).						
Revie	ewer's Name:Gina Casciano						
Phon	e: <u>703-605-0513</u> Division: <u>BPPD</u>						
Date:	3/4/10						



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 4, 2010

Nancy Huebl Senior Regulatory Specialist Wellmark International 1501 East Woodfield Road, Suite 200 W Schaumburg, Illinois 60173

Subject: Notification to Revise Storage and Disposal Statement per PRN 2007-4

Product Name: Zoecon® Granular IGR Cattle Supplement

EPA Reg. No: 2724-372

Your Submission Dated February 16, 2010

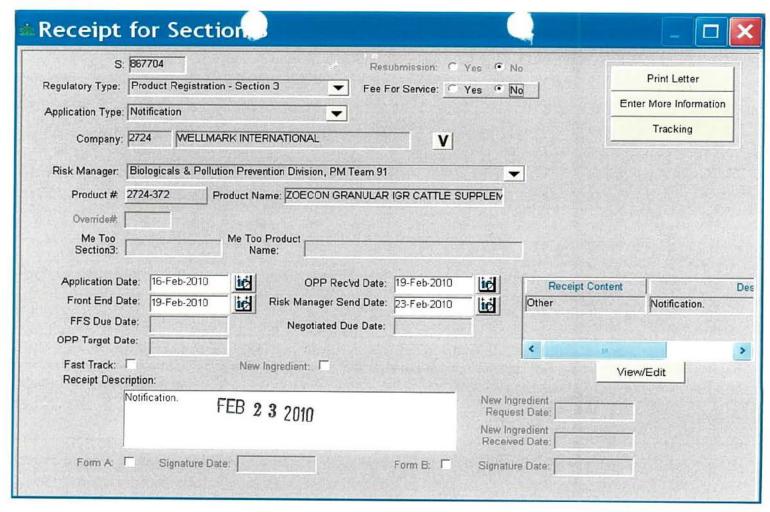
Dear Ms. Huebl:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 2007-4, dated above. A screen of the labeling revision request has been conducted for its applicability under PRN 2007-4, and it has been determined that the action request falls within the scope of this document. Our records have been duly noted, and the printed label with this application has been stamped "Notification, received and reviewed" and will be placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Casciano at (703) 605-0513 or via email at casciano.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)



such times of

Wellmar /ernational
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com



February 16, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Linda Hollis/BPPD Branch Chief

SUBJECT: NOTIFICATION PER PRN 2007-4/CONTAINER DISPOSAL

FOR ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT/EPA REG. NO. 2724-372

Dear Ms. Hollis:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted labeling to serve as notification per PRN 2007-4. The added text represents exact wording from the regulations/PR Notice, no other changes were made to the label. This action is not a PRIA action and does not require any fee.

If you have any questions, please, call me directly at 847/330-5376 or email me. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Huebl
Nancy Huebl

Sr. Registration Specialist nhuebl@central.com

enclosure

S EPA	Unit Environmental	ited States	gency	X	Registr Amend Other	ation	0-0060. Approval expires 2-28-9: OPP Identifier Number
		Application	n for Pesticide - Se	ection I			
Company/Product Number Wellmark International/2724-	-372		2. EPA Product Man Linda Hollis			3	B. Proposed Classification
Company/Product (Name) Wellmark International/Zoc	econ Granular IGR Cattle	Supplement	PM# Biopesticides				X None Restricted
5. Name and Address of Application Wellmark International 1501 East Woodfield Road Schaumburg, Illinois 60173 Check if this is a new control of the contro	Suite 200W 3	xde)	6. Expedited Rev (b)(i), my product EPA Reg. No.	is similar or id Date Rev	lentical in c	omposition a	110
			Section - II				
Notification of label change pe	to Agency letter dated . al page(s) if necessary. (For sever PRN 2007-4. This notification	cation is consiste	File Ag To on In II.)	inal printed laber gency letter date Me Too" Applicat ther - Explain be	ed tion elow.	he requirem	ents of EPA regulations at 40
CFR 156.10,156.140, 156.14 product. I understand that it is consistent with the requirement enforcement action and penalt	14, 156.146, and 156.156. N s a violation of 18 U.S.C. Se ents of 40 CFR 156.10,156.1	No other changes ec. 1001 to willfu 140, 156,144, 15	s have been made to th	ne labeling or the	he Confider	ntial Statem	ent of Formula for this
			Section - III				
1. Material This Product Will be	> Packaged In:		Section - III				
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ZOËCON® GRANULAR IGR CATTLE SUPPLEMENT

(Alternate Brand Name: ULTRALYX™ ULTRAMIN LOOSE MINERAL WITH ALTOSID® IGR)

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATEDICATION

A nutritional supplement containing S-methoprene* insect growth regulator for continuous / 4/10
feeding to cattle through the horn fly season

Reviewed By: Casciano

ACTIVE INGREDIENT:

S-Methoprene (CAS #65733-16-6)		0.02%
OTHER INGREDIENTS:		99.98%
	TOTAL	100.00%

GUARANTEED ANALYSIS (WILL VARY DEPENDING ON GEOGRAPHIC AREA AND REGIONAL FEEDING REQUIREMENTS)

TIEQUITE IN I	
Calcium (CA), not less than	13.2%
Calcium (CA), not more than	
Phosphorus (P), not less than	7.0%
Salt (NaCl), not less than	
Salt (NaCl), not more than	30.0%
lodine (I), not less than	0.015%
Vitamin A, not less than	
	USP units per pound

FEED INGREDIENTS

(AAFCO APPROVED FEED INGREDIENTS MAY VARY DEPENDING UPON NUTRITIONAL REQUIREMENTS IN DIFFERENT GEOGRAPHICAL REGIONS OF THE COUNTRY)

Vitamin A Acetate, D-Activated Animal Sterol (Source of Vitamin D₃-Stability Improved),
Dicalcium Phosphate, Defluorinated Phosphate, Calcium Carbonate, Low Fluorine Ground
Rock Phosphate, Soybean Meal, Salt, Iron Sulfate, Iron Oxide, Cobalt Carbonate, Silicon
Dioxide, Copper Carbonate, Petrolatum, Cane Molasses, Ethylene Diamine Dihydriodide,
Manganous Oxide, Zinc Oxide, Magnesium Oxide, Sodium Selenite

KEEP OUT OF REACH OF CHILDREN CAUTION

Use this product only as specified on the back of the bag. See back panel for additional Precautionary Statements

EPA Reg. No. 2724-372

EPA Est. No.

Lot Number: Net Weight:

^{*}As the Insect Growth Regulator ALTOSID®

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

This product contains high levels of copper. Consumption of this product by sheep or goats could result in copper toxicity. (Optional text - If product contains over 10 ppm copper).

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FEEDING AND MANAGEMENT INSTRUCTIONS

When used as directed Zoëcon® Granular IGR Cattle Supplement will provide sufficient S-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of horn fly season. Use the following management techniques to maintain continuous intake of Zoëcon Granular IGR Cattle Supplement at a level of ¹/₄ to ¹/₂ lb per 100 lb animal body weight per month.

- Assure cattle are not starved for nutrients in Zoëcon Granular IGR Cattle Supplement by providing them prior to feeding Zoëcon Granular IGR Cattle Supplement.
- Offer cattle 50 lb of Zoëcon Granular IGR Cattle Supplement for every 15 head of cattle.
- 3. Remove all other self-limiting nutritional supplements.
- Locate Zoëcon Granular IGR Cattle Supplement where cattle congregate (watering, loafing, shade areas).
- 5. Replenish Zoëcon Granular IGR Cattle Supplement on a regular basis as needed.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>below</u> ¹/₄ lb per 100 lb animal body weight per month increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- If intake of Zoëcon Granular IGR Cattle Supplement is <u>above</u> ¹/₂ lb per 100 lb animal body weight reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- Introduction of this product after an adult horn fly infestation is established will require treatment of cattle with adulticides if immediate elimination of the adult fly population is desired.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store Zoëcon Granular IGR Cattle Supplement in a cool place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container DisposalHandling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ALTOSID® Insect Growth Regulator and Zoëcon® are registered trademarks of Wellmark International.

Ultralyx™ is a trademark of Four Seasons Marketing, LLC

Wellmark International Schaumburg, Illinois 60173

Made in USA